

Application No.: 09/898,398

Applicant: Hutchison

Filed: July 3, 2001

Page 10 of 15

Remarks

Claims 1-61 were pending. By way of this response, the specification and drawings have been amended, claims 1-61 have been cancelled, and claims 62-81 have been added. Support for the amendments to the specification and drawings, and the new claims can be found in the application as originally filed, and no new matter has been added. Accordingly, claims 62-81 are currently pending.

Objections to Drawings

The drawings have been objected to for the labeling of panels of FIG. 2 and FIGS. 13-17.

As indicated hereinabove, attached are replacement sheets of drawings with the panels separately labeled, as suggested by the Examiner. Accordingly, Applicant submits the objection has been overcome.

Objections to the Specification

The specification has been objected to for various typographical errors.

As indicated above, the specification has been amended to correct the typographical errors and to address the amendments to the drawings. Accordingly, Applicant submits that the objection has been overcome.

Rejections Under 35 U.S.C. § 112, First Paragraph

The specification has been objected to under 35 U.S.C. § 112, first paragraph. In addition, claims 35 and 36 have been rejected under 35 U.S.C. § 112, first paragraph. In particular, and to the extent Applicant understands the Examiner's position, it appears that the objection and rejection of the claims is directed to subject matter regarding monoclonal and humanized

Application No.: 09/898,398
Applicant: Hutchison
Filed: July 3, 2001
Page 11 of 15

antibodies. Applicant's undersigned representative attempted to get verbal clarification from the Examiner regarding the objections, but the Examiner has not returned the undersigned's call.

Applicant has cancelled the previously pending claims, including claims 35 and 36, and submits that the new claims, and in particular claims 62-81, do not specifically recite monoclonal or humanized antibodies. Thus, Applicant submits the rejection has been overcome.

Nevertheless, Applicant further submits that a deposit of the antibodies was made in accordance with the Budapest Treaty (e.g., see page 15, line 25 to page 16, line 5; and the preliminary amendment filed September 7, 2001). In view of the deposit of biological material, Applicant submits the enablement requirement under 35 U.S.C. § 112, first paragraph has been satisfied.

In view of the above, Applicant submits that the objection to the specification and the rejection of the claims under 35 U.S.C. § 112, first paragraph has been overcome.

Rejections Under 35 U.S.C. § 112, Second Paragraph

Claims 1-26, 29-41, and 44-61 have been rejected under 35 U.S.C. § 112, second paragraph as allegedly indefinite for failing to particularly point out and distinctly claim the subject matter which Applicant regards as the invention.

As indicated above, claims 1-61 have been cancelled, and claims 62-81 have been added. Applicant respectfully traverses the rejection as it relates to the new claims.

Claim 62 includes the subject matter of previous claim 46 and 48. Claim 67 includes the subject matter of previous claims 23 and 26. Claim 70 includes the subject matter of claim 52 and 26. Claims 62, 67, and 70 include wording to address antecedence of "the bioactive, three dimensional epitope". In addition, claim 70 more clearly identifies the relevant portion of the hormone, and has addressed the antecedence of "the complex". Claim 74 has similarly been presented.

Application No.: 09/898,398
Applicant: Hutchison
Filed: July 3, 2001
Page 12 of 15

In view of the above, Applicant submits that the present claims, and in particular claims 62-81, are definite under 35 U.S.C. § 112, second paragraph.

Rejection Under 35 U.S.C. § 101

Claims 39, 42-43, and 60-61 have been rejected under 35 U.S.C. § 101.

Claims 1-61 have been cancelled. Applicant submits the rejection is moot.

Rejection Under 35 U.S.C. § 102

Claims 1-15, 18, 19, 21, 23-25, 27, 29, 30, 32-35, 37, 38, 40, 42-47, 49, 50, 52-55, 58, and 60 have been rejected under 35 U.S.C. § 102(b) as allegedly being anticipated by Kuronen et al. Claims 1-4, 6-15, 23-25, 27, 29, 30, 32-35, 37, 38, 40, 42-47, 49-55, and 60 have been rejected under 35 U.S.C. § 102(b) as allegedly being anticipated by Brown et al.

As indicated above, claims 1-61 have been cancelled. Therefore, Applicant submits the rejection is moot as to claims 1-61. Applicant respectfully traverses the rejections as they apply to the present claims, claims 62-81.

Applicant notes that claims 26 and 48 were not anticipated by the prior art. The present independent claims 62, 67, and 70 include subject matter of previous claims 26 and 48. In addition, claim 74 is directed to an isolated antibody that binds to a bioactive, three-dimensional epitope of the parathyroid hormone that includes a first portion located between amino acids 1-6 of SEQ ID NO: 1 and a second portion located between amino acids 7-13 of SEQ ID NO: 1.

Applicant submits that neither Kuronen et al. nor Brown et al. teach each and every limitation recited in the present claims, and therefore, the present claims, that is claims 62-81, are not anticipated by the prior art under 35 U.S.C. § 102.

Application No.: 09/898,398
Applicant: Hutchison
Filed: July 3, 2001
Page 13 of 15

Rejections Under 35 U.S.C. § 103

Claims 1-35, 37-50, 52-55, 58, 60, and 61 have been rejected under 35 U.S.C. § 103(a) as being unpatentable over Kuronen et al. in view of Gao et al. (1999) and John et al. Claims 51, 56, and 57 have been rejected under 35 U.S.C. § 103(a) as being unpatentable over Kuronen et al. in view of Gao et al. (1999) and further in view of Gao et al. (1996). Claim 59 has been rejected under 35 U.S.C. § 103(a) as being unpatentable over Kuronen et al. in view of Gao et al. (1999) and John et al. and further in view of Gao et al. (1996), and further in view of Immunotropics International.

As indicated above, claims 1-61 have been cancelled. Accordingly, the rejections are moot. Applicant respectfully traverses the rejections as they relate to new claims 62-81.

Applicant submits that the cited references, taken alone or in combination, do not disclose, teach, or suggest the present invention. For example, the references do not disclose, teach, or even suggest an antibody that recognizes and binds a bioactive, three-dimensional epitope of parathyroid hormone, the bioactive, three-dimensional epitope consisting of amino acids 1-13 of SEQ ID NO: 1, as recited in claims 67, let alone a kit comprising such an antibody, as recited in claim 62, or a method of detecting bioactive parathyroid hormone using such an antibody, as recited in claim 70. In addition, the references do not disclose, teach, or even suggest an antibody that recognizes and binds a bioactive, three-dimensional epitope of parathyroid hormone, the bioactive, three-dimensional epitope including a first portion located between amino acids 1-6 of SEQ ID NO: 1 and a second portion located between amino acids 7-13 of SEQ ID NO: 1, as recited in claim 74.

In rejecting the claims, the Examiner states that Gao et al. (1999) and John et al. teach the use of antibodies specific for residues 39-84 and 1-6 of human PTH. The Examiner further states that it would have been obvious to one of ordinary skill in the art to have substituted the antibodies isolated as specific fragments of PTH taught by Gao et al. and John et al. in the methods of

Application No.: 09/898,398

Applicant: Hutchison

Filed: July 3, 2001

Page 14 of 15

Kuronen et al for the detection of full length PTH discriminated from the truncated inactive PTH fragment present in patient samples. The Examiner contends that there would have been a reasonable expectation that antibodies specific for the fragment comprising residues 1-6 would also bind to the fragment consisting of residues 1-13.

Applicant submits that there is no motivation to combine the references, and that even if combined, the combination of references fails to disclose, teach, or suggest the present invention. In addition, Applicant vigorously disagrees that there would have been a reasonable expectation of success, as proposed by the Examiner. For example, an antibody that binds to amino acid residues 1-6 does not bind to a bioactive, three-dimensional epitope of parathyroid hormone, let alone an epitope which consists of amino acids 1-13 of SEQ ID NO: 1. Example 5 of the above-identified application demonstrates that both of the amino acid sequences, 1-6 and 7-13 are important for binding when targeting the bioactive, three dimensional epitope of parathyroid hormone (also see FIG. 10). As pointed out at page 37, lines 7-13, amino acid residues at two distinct regions of PTH, one region within amino acid residues 1-6, and the other region within amino acid residues 7-13 are important for antibody binding. Because the antibody fragments disclosed by Gao et al. and John et al. that bind to amino acid residues 1-6 do not bind to amino acid residues 7-13, the antibodies by Gao et al. and John et al. do not recognize and bind a conformational or nonlinear epitope of parathyroid hormone (i.e., a bioactive three-dimensional epitope).

Thus, Applicant submits that antibodies that recognize and bind to a bioactive, three dimensional epitope of parathyroid hormone, as recited in the present claims, are not disclosed or suggested by the prior art. Such antibodies provide an unexpected advantage of being able to recognize and bind three-dimensional epitopes of parathyroid hormone, as compared to the antibodies that bind linear epitopes, such as those disclosed by Gao et al. and John et al.

In view of the above, Applicant submits that the present claims, that is claims 62-81, are unobvious from and patentable over the prior art under 35 U.S.C. § 103.

Application No.: 09/898,398

Applicant: Hutchison

Filed: July 3, 2001

Page 15 of 15

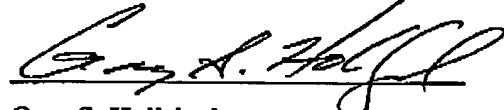
In addition, each of the present dependent claims is separately patentable over the prior art. For example, none of the prior art disclose, teach, or even suggest the present antibodies, kits, and methods including the additional feature or features recited in any of the present dependent claims. Therefore, applicant submits that each of the present claims is separately patentable over the prior art.

In view of the foregoing amendments and remarks, Applicant respectfully submits that the claims are not disclosed or suggested by the prior art, and respectfully submits that the claims are in condition for allowance. Notice of which is respectfully requested.

If a telephone interview would be of assistance in advancing prosecution of the subject application, Applicant's undersigned representative invites the Examiner to telephone him at the number provided below.

Respectfully submitted,

Date: 2/12/04



Greg S. Hollrigel
Registration No. 45,374
Stout, Uxa, Buyan & Mullins, LLP
4 Venture, Suite 300
Irvine, California 92618
Telephone: 949-450-1750

Attachments